K062933

5.0 510 (k) Summary

JAN 3 1 2007

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510 (k) Contact:	Bonnie Smith, RAC Synthes Spine Regulatory Affairs
Trade Name:	Oracle
Common / Classification Name:	Vertebral Body Replacement Device
Device Product Code and Classification:	MQP 21 CFR 888.3060: Class II
Predicate:	K011037 – Synthes Vertebral Spacer K010530 – Interpore Cross Geo™ Structure
Device Description:	The Synthes Oracle Spacer is a radiolucent vertebral body replacement device used in conjunction with supplemental fixation that provides structural stability in skeletally mature individuals following partial or total corpectomy. The Oracle Spacer has an oval shape and may be used to accommodate the anatomical requirements of the space created by the corpectomy. The spacer has an open architecture for packing bone graft material and it is available in various heights, cross-sectional sizes and lordosis angles to suit individual pathology and anatomical conditions.
Intended Use/ Indications for Use:	The Oracle Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial and total vertebrectomy procedures for the treatment of tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of the collapsed vertebral body. The Oracle Spacer is intended to be used with Synthes internal fixation systems, e.g., Pangea, USS (including Click'X), Small Stature USS, ATLP, TSLP, and Ventrofix. The interior of the spacer can be packed with bone (autograft or allograft). The Oracle Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

Substantial Equivalence:	Documentation has been provided that demonstrates that the Synthes Oracle Spacer is substantially equivalent to the previously cleared Synthes Vertebral Spacer (K011037) and the Interpore Cross Geo™ Structure (K010530).
Material:	Radiolucent polymer and titanium alloy materials in conformance with ASTM Standards.
Performance Data:	Mechanical test data is presented in conformance with the "Guidance for Spinal System 510(k)s", issued May 3, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SYNTHES Spine Co., L.P.
% Ms. Bonnie Smith, RAC
Regulatory Affairs Project Manager
1302 Wrights Lane East
West Chester, Pennsylvania 19380

JAN 3 1 2007

Re: K062933
Trade/Device Name: Synthes Oracle Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 8, 2006
Received: December 11, 2006

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

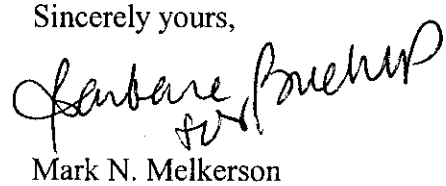
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K062933

Device Name: Oracle Spacer

Indications for Use:

The Oracle Spacer is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised during partial and total vertebrectomy procedures for the treatment of tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of the collapsed vertebral body. The Oracle Spacer is intended to be used with Synthes internal fixation systems, e.g., Pangea, USS (including Click'X), Small Stature USS, ATLP, TSLP, and Ventrofix. The interior of the spacer can be packed with bone (autograft or allograft).

The Oracle Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062933

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